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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ASHEN, JON BENJAMIN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,294	NIELSEN ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-5, 9-22, 25-40, 78 and 79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 3-5, 9-22, 25-40 and 78-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 1, 3-5, 9-22, 25-40, 78 and 79, in the reply filed on 11/05/2004 is acknowledged. However, upon reconsideration, the requirement for restriction mailed 10/06/2004 in this Application is withdrawn. A new requirement for restriction in this Application is set forth herein. Restriction to one of the following inventions is required under 35 U.S.C. 121:

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3-5, 18-20, 25-40 and 78-79, drawn to a method of treating mammalian cancer cells comprising contacting said cells with a p53 tumor suppressor protein and a microtubule affecting agent wherein said cells are first contacted with a p53 tumor suppressor protein and are subsequently contacted with paclitaxel or a paclitaxel derivative, classifiable in class 514, subclass 2.

II. Claims 3-5, 9-20, 25-40 and 78-79, drawn to a method of treating mammalian cancer cells comprising contacting said cells with a nucleic acid encoding p53 and a microtubule affecting agent wherein said cells are first contacted with a nucleic acid encoding p53 and are subsequently

contacted with paclitaxel or a paclitaxel derivative, classifiable in class 514, subclass 44.

III. Claims 3-5, 18-19, 21, 25-40 and 78-79, drawn to a method of treating mammalian cancer cells comprising contacting said cells with a p53 tumor suppressor protein and a microtubule affecting agent wherein said cells are first contacted with paclitaxel or a paclitaxel derivative and are subsequently contacted with a p53 tumor suppressor protein, classifiable in class 514, subclass 2.

IV. Claims 3-5, 9-19, 21, 25-40 and 78-79, drawn to a method of treating mammalian cancer cells comprising contacting said cells with a nucleic acid encoding p53 and a microtubule affecting agent wherein said cells are first contacted with paclitaxel or a paclitaxel derivative and are subsequently contacted with a nucleic acid encoding p53, classifiable in class 514, subclass 44.

V. Claims 3-5, 18-19, 22, 25-40 and 78-79, drawn to a method of treating mammalian cancer cells comprising contacting said cells with a p53 tumor suppressor protein and a microtubule affecting agent wherein said cells are contacted simultaneously with paclitaxel or a paclitaxel derivative and a p53 tumor suppressor protein, classifiable in class 514, subclass 2.

VI. Claims 3-5, 9-19, 22, 25-40 and 78-79, drawn to a method of treating mammalian cancer cells comprising contacting said cells with a p53 tumor suppressor protein and a microtubule affecting agent wherein said cells are contacted simultaneously with paclitaxel or a paclitaxel derivative and a nucleic acid encoding p53, classifiable in class 514, subclass 44.

3. Claim 1 link(s) inventions I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim I. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is a method of treatment comprising contacting cells with a protein and subsequently contacting cells with paclitaxel. Invention II is a method of treatment comprising contacting cells with a nucleic acid and subsequently contacting cells with paclitaxel. Each method utilizes a patentably distinct product. In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Invention I operates by the activity of the administered protein as it interacts with the biochemical machinery of the contacted cell. Invention II operates by gene expression or antisense inhibition, that being the activity of the administered nucleic acid as it interacts with the biochemical machinery of the contacted cell.

Furthermore, searching inventions I and II together would impose a serious search burden. In the instant case, prior art searches of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, searches of distinct method steps related to the administration of either proteins or nucleic acids. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of the inventions of groups I and II together.

5. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention III is a method of treatment comprising contacting cells with a with paclitaxel and subsequently contacting cells with a protein. Invention II is a method of treatment comprising contacting cells with a nucleic acid and subsequently contacting cells with paclitaxel. Each method utilizes a patentably distinct product. In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Invention III operates by the activity of the administered protein as it interacts with the biochemical machinery of the contacted cell. Invention IV operates by gene expression or antisense inhibition, that being the activity of the administered nucleic acid as it interacts with the biochemical machinery of the contacted cell.

Furthermore, searching inventions III and IV together would impose a serious search burden. In the instant case, prior art searches of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, searches of distinct method steps related to the administration of either proteins or nucleic acids. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of the inventions of groups I and II together.

6. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is a method of treatment comprising simultaneously contacting cells with paclitaxel and a protein. Invention II is a method of treatment comprising simultaneously contacting cells with paclitaxel and a nucleic acid. Each method utilizes a patentably distinct product. In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Invention V operates by the activity of the administered protein as it interacts with the biochemical machinery of the contacted cell. Invention VI operates by gene expression or antisense inhibition, that being the activity of the administered nucleic acid as it interacts with the biochemical machinery of the contacted cell.

Furthermore, searching inventions V and VI together would impose a serious search burden. In the instant case, prior art searches of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, searches of distinct method steps related to the administration of either proteins or nucleic acids. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of the inventions of groups V and VI together.

7. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions I-VI are outlined previously in this Action. In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation. Inventions I and II each operate by first contacting cells with protein (Invention I) or nucleic acid (Invention II) and subsequently contacting those same cells with paclitaxel or a paclitaxel derivative. Inventions III and IV each operate by first contacting cells with paclitaxel or a paclitaxel derivative and subsequently contacting those same cells with protein (Invention III) or nucleic acid (Invention IV). Inventions V and VI each operate by simultaneously contacting cells with protein (Invention V) or nucleic acid (Invention VI) and paclitaxel or a paclitaxel derivative. In each case, the order of addition of the protein, the nucleic acid and the paclitaxel that is required by what is now claimed, confers patentable distinctness to each of Inventions that are I-VI and as set forth previously in this Action, each of Inventions I-II, III-IV and V-VI are patentably distinct because each method utilizes a patentably distinct product (see sections 4-6 above).

Furthermore, searching any of Inventions I-VI together would impose a serious search burden. In the instant case, prior art searches of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, searches of distinct method steps related to the specific order of administration of

proteins or nucleic acids and paclitaxel or paclitaxel derivatives. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of Inventions I-VI together.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba